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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/539,748	03/31/2000	Peter L. Rosenblatt	R2005-700010	9371
37462	7590	10/04/2004	EXAMINER	
LOWRIE, LANDO & ANASTASI RIVERFRONT OFFICE ONE MAIN STREET, ELEVENTH FLOOR CAMBRIDGE, MA 02142			ODLAND, KATHRYN P	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/539,748

Applicant(s)

ROSENBLATT ET AL.

Examiner

Kathryn Odland

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 1-38 and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39 and 41-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Response to Amendment

This is a response to the amendment dated June 25, 2004. Claims 1-55 are pending. Claims 39 and 41-55 are under consideration. Claims 1-38 and 40 have been withdrawn from consideration.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 41 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Newly added claim 41 includes the recitation, "approximating a vaginal epithelium to at least one of a lateral pelvic sidewall and a sacrospinous ligament without exposing at least one of the lateral pelvic sidewall and the sacrospinous ligament through a surgical incision in the vaginal epithelium." Particularly the phrase, "sacrospinous ligament without exposing at least one of the lateral pelvic sidewall and the sacrospinous ligament through a surgical incision in the vaginal epithelium" is not supported in the specification. The specification on page 39 recites, "In addition, the fixation device may be applied to the sacrospinous ligament, which can also be palpated transvaginally, effecting vaginal vault suspension."

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However, there is no discussion of not exposing at least one of the lateral pelvic sidewall and the sacrospinous ligament through a surgical incision in the vaginal epithelium. Further, it is noted that the specification and the drawing are extremely vague and non-descriptive and would not enable one with ordinary skill in the art regarding the sacrospinous ligament. Moreover, the specification is extremely vague overall giving general broad recitations rather and descriptive method steps. Any rejections are as best understood.

3. Claims 47, 48 and 54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not support that stated in claims 47 and 48 as discussed above.

Response to Arguments

4. Applicant's arguments with respect to claim 39 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 39, 41, 46-49 and 52-55 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kovac in US Patent No. 6,039,686.

Regarding claims 39 and 41, Kovac discloses a method of repair via placing a soft tissue fixation device (such as via sutures and mesh support) vaginally without exposing the lateral pelvic sidewall through a surgical incision in a vaginal wall, as recited throughout the specification with emphasis on columns 5-8 and seen in the figures. A insertion device is obvious if not inherent.

Regarding claim 46, Kovac discloses that as applied to claim 41 as well as anchors and sutures.

Regarding claim 47 and 48, Kovac discloses that as applied to claim 41. Further, approximating at least one of an arcus tendineus fascia of the pelvis and a structure of a levator ani for paravaginal repair of a rectocele is within the scope of the invention and would be obvious if not inherent.

Regarding claim 49, Kovac discloses that as applied to claim 41 as well as prolapse repair.

Regarding claim 52, Kovac discloses a method of soft tissue repair via the vagina by penetrating an intact outer wall of a first soft tissue; penetrating a second soft tissue and affixing the first soft tissue to the second without exposing one of the first and second tissue through a surgical incision in the other tissue, via sutures etc. as recited throughout the specification.

Regarding claims 53-55, Kovac discloses that as applied to claim 41 as well as it is obvious if not inherent to do so without making an incision in the pelvic sidewall.

7. Claims 39, 41, 46-49 and 52-55 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Benderev et al. in US Patent No. 6,500,194.

Regarding claims 39 and 41, Benderev et al. disclose a method of repair via placing a soft tissue fixation device (such as staples) vaginally without exposing the lateral pelvic sidewall through a surgical incision in a vaginal wall, as recited throughout the specification with emphasis on column 38, lines 30-60. Further, Benderev et al. discloses an insertion device (502).

Regarding claim 46, Benderev et al. disclose that as applied to claim 41 as well as anchors (such as staples, etc.).

Regarding claim 47 and 48, Benderev et al. disclose that as applied to claim 41. Further, approximating at least one of an arcus tendineus fascia of the pelvis and a structure of a levator ani for paravaginal repair of a rectocele is within the scope of the invention and would be obvious if not inherent.

Regarding claim 49, Benderev et al. disclose that as applied to claim 41. Prolapse repair is obvious if not inherent.

Regarding claim 52, Benderev et al. obviously if not inherently disclose a method of soft tissue repair via the vagina by penetrating an intact outer wall of a first soft tissue; penetrating a second soft tissue and affixing the first soft tissue to the second without exposing one of the first and second tissue through a surgical incision in the other tissue, via sutures etc. as recited throughout the specification with emphasis on column 38, lines 30-60.

Regarding claims 53-55, Benderev et al. disclose that as applied to claim 41 as well as it is obvious if not inherent to do so without making an incision in the pelvic sidewall.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kovac in US Patent No. 6,039,686 or Benderev et al. in US Patent No. 6,500,194 in view of Thompson in US Patent No. 5,591,163.

Kovac and Benderev et al. disclose that as applied to claim 41. However, a template is not explicitly recited. On the other hand, Thompson teaches to use a template to properly direct a surgical procedure to a target site. Thus, it would be obvious to one with ordinary skill in the art to use a template in the systems of Kovac and Benderev et al. for the purpose of proper placement of the fixation device.

11. Claims 44, 45, 50 and 51 rejected under 35 U.S.C. 103(a) as being unpatentable over Kovac in US Patent No. 6,039,686 or Benderev et al. in US Patent No. 6,500,194.

Regarding claims 44 and 45, Kovac and Benderev et al. disclose that as applied to claim 41. Claims 44 and 45 are directed to a particular species, such as that shown in figure 15. The current application does not recite any criticality for any particular species. Thus, they can be considered equivalents. Therefore, it

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considered an equivalent having species with or without a remover.

Nonetheless, including a remover would be obvious to one with ordinary skill in the art for the purpose of repositioning and removing the device.

Regarding claims 50 and 51, Kovac and Benderev et al. disclose that as applied to claim 41. Further, guiding using MRI, CT scan, etc is extremely well known in the art and would be obvious if not inherent to one with ordinary skill in the art.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

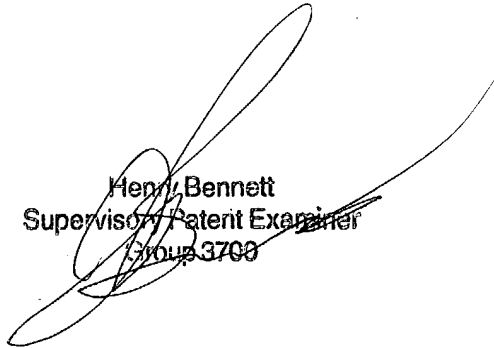
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KO



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